

Executive Summary

Washington's Children's Safe Products Act (CSPA), passed in 2008, requires the Department of Ecology, in consultation with the Department of Health, to develop a list of chemicals of high concern for children and to establish rules for manufacturers of children's products to report on their use of these chemicals. This report describes the process Ecology used, to develop the first such list of chemicals.

The CSPA marks a significant departure from other laws aimed at reducing the threats and impacts caused by the continued and increasing use of toxic chemicals throughout our economy. Rather than addressing one chemical or product at a time, this law addresses one of the biggest challenges to the development of more effective policies regarding toxic chemicals – lack of data. Information reported under the CSPA will be used by policy makers to determine what, if any, further actions might be required to assure consumers that children's products on the shelves are safe.

It is important to note that mere presence of chemicals of concern in a children's product does not mean that exposure to those chemicals is occurring, nor does it mean that the product is unsafe. If further actions, beyond reporting, are needed to protect consumers, additional legislation would be required.

List development process

Limited resources and lack of data led us to consider how to use the information we do have to best achieve the goals of the law. We knew we'd need to build on the work of others and we knew that any list we developed would have to be dynamic– adaptable to new science and emerging information. We established a goal of about 50 chemicals for the first reporting list, knowing also that the **first list is just that – a starting point**. As additional information is considered and evaluated, the list will be modified and the rule amended.

The CSPA established the criteria to be used in identifying chemicals of concern but did not include a process to be used to prioritize them. With tens of thousands of chemicals in commerce, we needed to develop a method to relatively quickly prioritize chemicals using readily available information.

Creation of the initial list of chemicals of high concern for children is being done in three phases. Building the list was done in Phase 1, prioritization in Phase 2 and final vetting in Phase 3.

Phase 1 – Building

In Phase 1, we began by identifying authoritative sources of information on toxicity and potential for exposure. This process is explained in detail in the July, 2009 report to the legislature.¹ We identified about 2000 chemicals that appeared to meet the statutory definition of a high priority chemical. We then identified about 2000 chemicals that appeared to meet the statutory criteria for potential for exposure. The overlap between these two lists (about 500 chemicals) was the starting point for refinement of the list.

For convenience we labeled this list of approximately 500 chemicals as potential Chemicals of High Concern for Children (CHCCs). This list was further narrowed by removing chemicals that are:

- lacking a chemical abstract service number (CAS)
- regulated under FIFRA, CPSIA or TSCA
- already banned in WA (e.g. PBDEs)
- combustion byproducts (e.g. dioxin)
- emerging chemicals (i.e. those chemicals removed because the science was not sufficiently robust to demonstrate toxicity)
- environmental toxicants (i.e. the listing source included the chemical primarily because of environmental toxicity and not human toxicity)

Phase 2 – Prioritization

The Agencies were interested in additional children's environmental health expertise to assist us in prioritizing chemicals and formulating the final reporting list of CHCCs. Ecology and DOH contracted with Dr. Catherine Karr, a nationally recognized expert in children's health with the University of Washington Pediatric Environmental Health Specialty Unit. Dr. Karr provided scientific and technical expertise and advice and developed the prioritization algorithm.

Dr. Karr proposed a framework to qualitatively evaluate the evidence for toxicity and potential for exposure for each of the chemicals being considered for the initial reporting list based upon a weight-of-evidence approach. Results from this prioritization process were placed into the following matrix. Chemicals that received the designation as "worst" have the strongest evidence of human toxicity. Similarly, chemicals ranked as "known" had the strongest evidence of exposure potential.

¹ Washington State Department of Ecology. [Child Safe Products Act Draft Report](#). April 2009. Publication No. 09-07-014

TOXICITY Score		EXPOSURE Score		
		Known	Possible	Unlikely
	Worst	W/K	W/P	W/U
	Severe	S/K	S/P	S/U
	Bad	B/K	B/P	B/U

Toxicity Evaluation

Compared to adults, from the fetal period until adulthood, a child experiences rapid ongoing organ system development and a long potential lifespan that may allow time for development of chronic disease later in life. Based on this, the chemicals of primary concern include those that interfere with the normal development in addition to those that are potential carcinogens.

The framework for evaluating toxicity is designed to develop a profile that considers the following core components:

- Evidence describing the chemical with respect to endpoints of highest concern for children: developmental and reproductive toxicity, endocrine disruption, cancer.
- Strength and weight of the evidence for those health endpoints.

Exposure Potential Evaluation

Two perspectives of exposure concern are considered:

- The potential for exposure to an individual child from use of the product
- The potential for exposure to the population of children from the chemical being in multiple children's products or consumer products in general.

Results of Phase 2 Prioritization

177 chemicals were evaluated for toxicity and exposure potential and then placed in the matrix.

We chose all chemicals scored as "known" to be considered for the draft reporting list. All of these chemicals were either found in people as reported by the CDC in the National Health and Nutrition Examination Survey (NHANES) or were documented as being present in children's products. Clearly any chemical found in people is evidence that some route of exposure has already occurred while chemicals found in children's products is evidence of the potential for exposure from the product.

In addition, we decided to include all the persistent, bioaccumulative and toxic chemicals (PBTs) from the list of 177 potential CHCCs (adding 5 additional chemicals).

These chemicals have already been identified as the “worst of the worst” and while the evidence of exposure is weak for a few of these chemicals, we want to know if they are in children’s products.

Sixty-six chemicals were identified from the Phase 2 prioritization step as appropriate for the draft reporting list.

Phase 3 – Vetting

Phase 3 was a more thorough vetting of each of the chemicals from Phase 2. As a starting point for this vetting effort, both alcohol and quartz were removed from the list. Additionally the metals were grouped (i.e. Arsenic and Arsenic-containing compounds). As a result there were 66 chemicals which went through further Phase 3 evaluation. This additional evaluation resulted in the removal of the following chemicals: Benzoic Acid, Propylene Glycol, Diethyl Ether, and MEHP.

In addition to a more in-depth assessment of the toxicity information and potential for exposure to each Phase 2 chemical, Phase 3 included development of recommended reporting trigger levels. At the request of Ecology, the recommended trigger levels are not health-based. The specifics on the process used to develop them can be found in the report submitted by DOH. Ecology also confirmed that analytical methods were available for each chemical.

Ecology thinks the reporting system outlined in the rule will provide the information needed to determine if additional actions are necessary to protect children, while still being practical and enforceable. It is not our intent to conduct risk assessments of each product, nor does the law require this. It is beyond our current and foreseeable resources to determine if every individual product is ‘safe.’

Pilot Rulemaking

The CSPA represents a new approach to addressing the use of toxic chemicals in products. As such, we felt it would be prudent to use a unique provision of Washington’s Administrative Procedures Act. This provision allows both the agency and the regulated parties to “try out” the rule before it becomes effective. The pilot phase report highlights what we learned during this process.

Now that the pilot phase is complete, we will enter into more traditional rulemaking where the public and stakeholders can formally comment on the draft rule.